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TO:		
Examiner Mike Brannock	U.S. Patent and Trademark Office	703-746-5238
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MESSAGE:

Applicant: Monty Krieger and Susan L. Acton

Serial No.: 08/765,108 Art Unit: 1646

Filed: March 27, 1997 Examiner: John Ulm

For: *CLASS BI AND CI SCAVENGER RECEPTORS*

MIT6620

The opinion in support of the decision b ing entered today was not written for publication and is not binding precedent of the Board.

Paper No. 26

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte MONTY KRIEGER and SUSAN L. ACTON

Appeal No. 1997-3321
Application No. 08/265,428

ON BRIEF

Before WILLIAM F. SMITH, SCHEINER and ADAMS, Administrative Patent Judges.

ADAMS, Administrative Patent Judge.

REMAND TO THE EXAMINER

On consideration of the record we find this case is not in condition for a decision on appeal. For the reasons that follow, we remand the application to the examiner to consider the following issues and to take appropriate action.

Docketed for_____
By: QB
Date: 10-11-01

Claim 1[1] is illustrative of the subject matter on appeal and is reproduced below:

1. An isolated scavenger receptor protein type BI which selectively binds to low density lipoprotein and to modified lipoprotein having the characteristics of acetylated low density lipoprotein consisting of the amino acid sequence shown in Sequence ID No. 4 or the sequence having conservative substitutions, additions and deletions thereof.

The reference relied upon by the examiner is:

Calvo et al. (Calvo), "Identification, Primary Structure, and Distribution of CLA-1, a Novel Member of the CD36/LIMPII Gene Family," J. Biol. Chem., Vol. 268, No. 25, pp. 18929-18935 (1993)

GROUNDS OF REJECTION[2]

Claims 1, 2 and 6-8 stand rejected under 35 U.S.C. § 112, first paragraph, as failing to provide an enabling disclosure and an adequate written description for an isolated human type BI scavenger receptor protein.[3]

Claims 1-4 and 6-8 stand rejected under 35 U.S.C. § 112, first paragraph, as being based on an insufficient disclosure to support or enable the scope of the claimed invention.

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[1] We note the examiner's statement (Answer, page 3) "[c]laims 1 and 3 contain errors as presented in the Appendix to the [B]rief. Accordingly, claims 1 and 3 are correctly written in the Appendix to the examiner's [A]nswer." See also appellants' amendment (Page 10, received February 12, 1996) at page 2. Claim 1 is correctly reproduced herein.

[2] We note the examiner statement (Answer, page 2) that "[c]laim 5 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claim.

[3] We not the rejection of claims 1, 2 and 6-8 is directly connected and relates to the objection to the sp cification. In re Hengehold, 440 F.2d 1395, 1403-1404, 169 USPQ 473, 479-480 (CCPA 1971).

Claims 1-8 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particular point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-4 and 6-8 stand rejected under 35 U.S.C. 103 as obvious over Calvo.

We remand.

DISCUSSION

The briefings presented to the Board by both appellants and the examiner do not allow this Merits Panel to perform a reasoned review of either parties position.

1. Improper Examiner's Answer.

In setting forth the rejections in the Answer[4], the examiner refers to Paper Numbers 6 and 14. See e.g., Answer, page 9. This is improper.

In relevant part, the Manual of Patent Examining Procedure (MPEP) § 1208 (6th ed., July 1996), states "[a]n examiner's answer should not refer, either directly or indirectly, to more than one prior Office action."

2. Appellants failed to address the issues under 35 U.S.C. § 112, second paragraph.

According to appellants (Brief[5], page 13) "[t]he objections as to indefiniteness have been responded to in the accompanying Amendment." This amendment was not entered. See Answer, page 2. We note appellants'

[4] Paper No. 22, mailed March 26, 1997.
[5] Pap r No. 21, received February 18, 1997.

statement (Brief, page 13) "[i]n the event this amendment is not entered and the claims are found otherwise patentable, remand to the [e]xaminer to resolve these issues is earnestly solicited." This is not a response to the rejections under 35 U.S.C. § 112, second paragraph. As set forth in 37 C.F.R. § 1.192(c)(8) (1996) "[t]he brief shall contain ... [t]he contentions of appellant with respect to each of the issues presented for review...."

As set forth in 37 C.F.R. § 1.192(d) (1996) "[i]f a brief is filed which does not comply with all the requirements of paragraph (c) of this section, appellant will be notified of the reasons for non-compliance and provided with a period of one month within which to file an amended brief...." We note the examiner did not notify appellants of the defective Brief, nor does the Answer respond in any way to the absence of an argument with regard to the rejections under 35 U.S.C. § 112, second paragraph.

We remind both the examiner and appellants that analyzing claims based on "speculation as to meaning of the terms employed and assumptions as to the scope of such claims" is legal error. In re Steele, 305 F.2d 859, 862, 134 USPQ 292, 295 (CCPA 1962).

3. Failure of the examiner to address appellants' response to the rejection of claims 1-4 and 6-8 under 35 U.S.C. § 112, first paragraph:

At page 13 of the Brief, appellants' first refer to a "proposed amendment", then they argue:

> it must be understood that functional equivalents would be readily apparent t those skilled in th art who understand that many regions of the protein clearly are not involved in biological function

> other than in a peripheral mann r, and could be easily and predictably replaced with structurally related amino acids.

The examiner, however, fails to respond to this argument.

4. Claim Groupings:

While the examiner acknowledges (Answer, bridging paragraph, pages 2-3), appellants' "grouping of claims", the examiner fails to separately address each group.

Accordingly, we remand the application to the examiner to provide him with an opportunity to correct the errors on this record.

OTHER ISSUES

In the interest of judicial economy, we make the following observations based on our understanding of the claim and the briefings of both the examiner and appellants.

1. The rejection of claims 1, 2 and 6-8:

According to the examiner (Answer, page 3) the specification fails "to provide an enabling disclosure and an adequate written description for an isolated human type BI scavenger receptor protein." The examiner however, failed to argue the issue of enablement separately from the issue of "written description."

The written description provision is separate and distinct from the enablement requirement. Vas-Cath, 935 F.2d at 1560, 19 USPQ2d at 1114. To satisfy the written description requirement, a patent specification must describe the claimed invention in suffici nt detail that one skilled in the art can reasonably

conclude that the inventor had possession of the claimed invention. Vas-Cath, 935 F.2d at 1563, 19 USPQ2d at 1116. The enablement requirement of 35 U.S.C. § 112, first paragraph, requires that the patent specification enable "those skilled in the art to make and use the full scope of the claimed invention without 'undue experimentation.'" Genentech, Inc. v. Novo Nordisk. A/S, 108 F.3d at 1365, 42 USPQ2d at 1004 (quoting In re Wright, 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)).

As set forth in Purdue Pharma L.P. v. Faulding Inc., 230 F.3d 1320, 1323, 56 USPQ2d 1481, 1483 (Fed. Cir. 2000) the written description "inquiry is a factual one and must be assessed on a case-by-case basis." Furthermore, "the PTO has the initial burden of presenting evidence or reasons why persons skilled in the art would not recognize in the disclosure a description of the invention defined by the claims." In re Wertheim, 541 F.2d 257, 263, 191 USPQ 90, 97 (CCPA 1976). As set forth in Wertheim, 541 F.2d at 1262, 191 USPQ at 96:

> The function of the description requirement is to ensure that the inventor had possession, as of the filing date of the application relied on, of the specific subject matter later claimed by him; how the specification accomplishes this is not material. In re Smith, 481 F.2d 910, 178 USPQ 620 (CCPA 1973), and cases cited therein. It is not necessary that the application describe the claim limitations exactly, In re Lukach, [442 F.2d 967, 169 USPQ 795 (1971]... but only so clearly that persons of ordinary skill in the art will recognize from the disclosure that appellants invented processes including those limitations. In re Smythe, 480 F.2d 1376, 1382, 178 USPQ 279, 284 (CCPA 1973).
>
> The primary consideration is *factual* and depends on the nature of the invention and the amount of knowledge imparted to those skilled in the art by the disclosure.

In considering the issue of nablement, we note that in order to satisfy the enablement requirement of 35 U.S.C. § 112, first paragraph, a patent application must adequately disclose the claimed invention so as to enable a person skilled in the art to practice the invention at the time the application was filed without undue experimentation. Enzo Biochem, Inc. v. Calgene, Inc., 188 F.3d 1362, 1371-72, 52 USPQ2d 1129, 1136 (Fed. Cir. 1999). We note, however, that "nothing more than objective enablement is required, and therefore it is irrelevant whether this teaching is provided through broad terminology or illustrative examples." In re Marzocchi, 439 F.2d 220, 223, 169 USPQ 367, 369 (CCPA 1971). As set forth in In re Wright, 999 F.2d 1557, 1561-62, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993):

> When rejecting a claim under the enablement requirement of section 112, the PTO bears an initial burden of setting forth a reasonable explanation as to why it believes that the scope of protection provided by that claim is not adequately enabled by the description of the invention provided in the specification of the application; this includes, of course, providing sufficient reasons for doubting any assertions in the specification as to the scope of enablement.

With regard to the examiner's burden of setting forth a reasonable explanation as to why he believes the specification does not enable the claimed invention, we note that determining whether the disclosure is enabling, is a legal conclusion based on several underlying factual inquiries. See In re Wands, 858 F.2d 731, 735, 736-37, 8 USPQ2d 1400, 1402, 1404 (Fed. Cir. 1988). As set forth in Wands, the factors to be considered in determining whether a claimed invention is enabled throughout its scope without undue experimentation include

the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claims.

We recommend that the examiner review Enzo Biochem, Inc. v. Calgene, Inc., 188 F.3d 1362, 52 USPQ2d 1129 (Fed. Cir. 1999). Therein, the court provided a model analysis of enablement issues and illustrated the type of fact finding which is needed before one is in a proper position to determine whether a given claim is enabled or non-enabled.

By addressing the written description and enablement provisions of 35 U.S.C. § 112, first paragraph together, the examiner failed to focus on the requirements of either provision. Therefore, in the event of further prosecution, the examiner should evaluate enablement separately from written description.

2. The rejection under 35 U.S.C. § 103:

We emphasize the examiner's discussion of Calvo (Answer, page 10) wherein the examiner finds that Calvo "suggested that CLA-1 might be a cell surface receptor protein ... postulated [CLA-1] to be a cell surface protein ... [and that] CLA-1 was suspected of being 'a receptor for extracellular products'" [emphasis added]. Calvo teach (page 18934, bridging sentence, columns 1 and 2) that "[s]o far it is difficult to envisage a function for CLA-1, but if its location on the plasma membrane is confirmed, one could speculate on the basis of its structural homology to CD36 that CLA-1 could act as a receptor for extracellular products" [emphasis added].

However, we remind the examiner, if the prior art does not teach any specific or significant utility for the disclosed compounds, then the prior art is not sufficient to render structurally similar claims prima facie obvious because there is no motivation for one of ordinary skill in the art to make the reference compounds, much less any structurally related compounds. In re Stemniski, 444 F.2d 581, 586, 170 USPQ 343, 348 (CCPA 1971).

The examiner cites no authority upon which to maintain his rejection in view of Stemniski.

3. The Declaration filed under 37 C.F.R. § 1.131:

We note that appellants rely (Brief, pages 12) on their declaration demonstrating the cloning and expression of hamster protein, and hybridization of hamster nucleic acid to the mouse gene, in an attempt to antedate the Calvo reference relied upon by the examiner. We further note that appellants admit (Declaration[6], paragraph 2) is the human homologue of the hamster class B1 scavenger receptor protein. If prosecution is resumed, appellants should take the opportunity to discuss their position in view of In re Bell, 991 F.2d 781, 26 USPQ2d 1529 (Fed. Cir. 1993) and In re Deuel, 51 F.3d 1552, 34 USPQ 1210 (Fed. Cir. 1995). As set forth in Deuel, 51 F.3d at 1559, 34 USPQ at 1215 "[w]e today reaffirm the principle, stated in Bell, that the existence of a general method of isolating cDNA or DNA molecules is essentially irrelevant to the question whether the specific molecules themselves would have been obvious...."

[6] Paper No. 13, received May 3, 1996.

Appeal No. 1997-3321
Application No. 08/265,428

We state that we are not authorizing a Supplemental Examiner's Answer under the provisions of 37 CFR § 1.193(b)(1). Any further communication from the examiner that contains a rejection of the claims should provide appellants with a full and fair opportunity to respond.

This application, by virtue of its "special" status, requires an immediate action. MPEP § 708.01(D) (7th ed., rev. 1, February 2000). It is important that the Board be informed promptly of any action affecting the appeal in this case.

REMANDED

William F. Smith
Administrative Patent Judge

Toni R. Scheiner
Administrative Patent Judge

Donald E. Adams
Administrative Patent Judge

) BOARD OF PATENT
) APPEALS AND
) INTERFERENCES

DA/dym

Appeal No. 1997-3[illegible]
Application No. 08/265,428

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appeal
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435 F.2d 1340
168 U.S.P.Q. 372
(Cite as: 58 C.C.P.A. 797, 435 F.2d 1340)

United States Court of Customs and Patent Appeals.

Application of Abner B. STRYKER, Jr.

Patent Appeal No. 8420.

Jan. 14, 1971.

Appeal from decision of the Board of Appeals of United States Patent Office, Serial No. 272,449, affirming rejection of both claims in application for improved process for producing polypropylene. The Court of Customs and Patent Appeals, Lane, J., held that where difference between claimed invention and reference disclosure were so small as to render claims obvious over reference, antedating affidavit submitted on claimant's behalf by representative of assignee of application removed reference disclosure as a reference notwithstanding affidavit, while alleging conception and reduction to practice of claimed improved process, including weight percentage limitations, before reference filing date, failed to show corroborating evidence of such weight percentage limitations.

Reversed.

West Headnotes

[1] Patents ⇐16.25
291k16.25
(Formerly 291k18)

Claimed invention of flashing a suspension containing about 50-60 percent by weight polypropylene in liquid propylene to obtain a polymer containing not in excess of about two percent by weight propylene did not produce any unexpected results and it did not render claimed process unobvious over prior process involving separation of polypropylene from propylene by flashing of monomer from polymer in cyclone-type flash zone using mixture containing 35 percent solids by weight.

[2] Patents ⇐16.25
291k16.25
(Formerly 291k18)

Where difference between claimed invention and reference disclosure was so small as to render claims obvious over reference, antedating affidavit submitted on claimant's behalf by representative of assignee of application removed reference disclosure as a reference notwithstanding affidavit, while alleging conception and reduction to practice of claimed improved process for producing polypropylene, including weight percentage limitations, before reference filing date, failed to show corroborating evidence of such weight percentage limitations. 35 U.S.C.A. § 103.

Patents ⇐328(2)
291k328(2)

3,197,453. Cited as reference.

**1340 *797 Fred S. Valles, Ronald J. Carlson, Paramus, N.J., attorneys of record, for appellant.

S. Wm. Cochran, Washington, D.C., for the Commissioner of Patents; Jack E. Armore, Washington, D.C., of counsel.

Before RICH, ALMOND, BALDWIN, and LANE, Judges, and NEWMAN, Judge, United States Customs Court, sitting by designation.

LANE, Judge.

This appeal is from the decision of the Patent Office Board of Appeals, which affirmed the rejection of both claims in appellant's application *798 serial No. 272,449, filed April 11, 1963, for an improved process for producing polypropylene. We reverse.

The invention is defined, and also adequately described for our purposes, by claim 1:

The process of removing propylene diluent from a suspension consisting essentially of from about 50%-60% By weight polypropylene in liquid propylene obtained directly from a propylene polymerization reactor under the autogenous pressure of the reactor which consists essentially in feeding the said suspension from the reactor to a recovery zone of the cyclone type **1341 maintained at substantially atmospheric pressure, whereby propylene diluent is flashed from the solid particles of polypropylene, leaving on said particles

not in excess of about 2% By weight propylene, and recovering the thus treated polypropylene.

The claims were rejected as obvious over Harban, [FN1] who discloses separation of polypropylene from propylene by flashing of monomer from polymer in a cyclone-type flash zone. The Harban mixture is disclosed as containing 35% Solids by weight, and the patent indicates that the separation achieved is nearly perfect, but does not state a specific percentage of separation.

FN1. U.S. patent 3,197,453, issued July 27, 1965, on an application filed July 11, 1961.

[1] Appellant contends that he discovered that, unexpectedly, the use of a suspension containing 50-60% By weight polymer permitted direct discharge of the suspension into a flashing zone maintained at atmospheric pressure, and resulted in a residual monomer level of 2% Or less. We have considered appellant's arguments on this point, but we agree with the Patent Office that appellant's polymer concentration does not produce any unexpected results and does not render the claimed process unobvious over Harban.

We turn now to appellant's alternative contention, i.e., even if the claimed processes are obvious over Harban, Harban is removed as a reference by the antedating affidavit submitted on appellant's behalf by a representative of the assignee of the application. [FN2] The board considered the affidavit deficient in that, while it alleged conception and reduction to practice of the claimed process, including the weight percentage limitations, before the Harban filing date, there was no corroborating evidence showing those weight percentage limitations. The board stated:

FN2. An additional affidavit submitted by appellant's attorney stated that appellant had left the assignee's employ, was in a relatively inaccessible area of Peru, and hence was unavailable to execute the affidavit himself.

The claimed invention must be shown in the affidavit, i.e., the alleged essence of the invention of flashing a suspension containing about 50%-60% By weight polypropylene in liquid propylene to obtain a polymer containing not in excess of about 2% By weight propylene must at least be demonstrated therein. In re Tanczyn, 52 CCPA 1630; 146 USPQ 298, 347 F.(2d) 830; 821 OG 849 (1965).

*799 [2] We think the board erred in applying Tanczyn to the facts of this case. In Tanczyn we limited to a certain extent the language we used in In re Stempel, 241 F.2d 755, 44 CCPA 820 (1957), wherein we had stated that 'all the applicant can be required to show is priority with respect to so much of the claimed invention as the reference happens to show.' It will be recalled that in Tanczyn the appellant sought to remove a reference by an affidavit which showed prior possession by the appellant of subject matter on which the claims did not read but which corresponded to the subject matter disclosed in the reference sought to be removed. We found the affidavit insufficient to remove the reference, but we held the claims to be unobvious over the reference. In other words, the subject matter shown in the reference and the affidavit was so different from the claimed invention that the claims were unobvious and patentable over the reference. In the case before us the differences between the claimed invention and the reference disclosure are so small as to render the claims obvious over the reference. The features which the board found inadequately corroborated by appellant's evidence are the very features considered insufficient to patentably distinguish over the Harban reference. To hold that Harban is not removed by the showing here presented would lead to an anomalous result, i.e., if appellant broadened his claims by deleting the weight limitations, **1342 so as to read literally on Harban, Harban would not be available as a reference against such broadened claims because appellant's antedating affidavit would be satisfactory in every respect. [FN3] It cannot be the law that the same affidavit is insufficient to remove the same reference applied against the slightly narrower claims presented here.

FN3. We recognize that, had appellant presented broader claims, the Patent Office might have found other, earlier art on which to reject them.

For the foregoing reasons, the board's rejection of the claims as unpatentable over Harban, under 35 U.S.C. § 103, is reversed.

*797 Reversed.

END OF DOCUMENT